

JUL 16 1996

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510(k) Summary

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Date Summary Prepared: December 27, 1995

Device Name: Mouse Anti-Human T-cell, CD3/FITC, UCHT1 +
Mouse Anti-Human T-cell, CD4/RPE, MT310

Device Classification: Class II according to 21 CFR 864.5220, on the basis that monoclonal antibodies are accessories for automated differential cell counters.

Panel: This device classification is under the Hematology and Pathology devices panel, Division of Clinical Laboratory Devices.

Product Code: GKZ

Predicate Device(s): DAKO Monoclonal Mouse Anti-Human T-cell, CD3/FITC, UCHT1 (DAKO Code Number F0818, FDA K942797) and
DAKO Monoclonal Mouse Anti-Human helper/inducer T-cell, CD4/RPE, Clone MT310 (DAKO Code Number R0805, FDA K945212)

Device Description: Purified mouse anti-human CD3, Clone UCHT1, conjugated with fluorescein isothiocyanate, isomer 1 (FITC) + purified mouse anti-human CD4, Clone MT310, conjugated with R-phycoerythrin, present in 0.05M Tris-HCl buffer, pH 7.2, 15 mM NaN₃, 0.1M NaCl, stabilized with 1% carrier protein

Subpopulations of lymphocytes may be stained with fluorochrome-conjugated antibody and evaluated in peripheral blood specimens when contaminating red blood cells (RBC's) are lysed prior to flow cytometric analysis. A subpopulation of WBC's are selected for assessment based upon cell morphology.

Intended Use: For *In Vitro* Diagnostic Use

Mouse Anti-Human T-cell, CD3/FITC, UCHT1 + Mouse Anti-Human T-cell, CD4/RPE, MT310 (DAKO Anti-CD3/FITC and Anti-CD4/RPE) has been developed for use in flow cytometry for the analysis of CD3⁺ and CD4⁺ T-cells. This reagent allows simultaneous detection and quantification of CD3⁺CD4⁺ cells (CD4 positive T-lymphocytes) in normal and pathological conditions such as immunodeficiency disorders. It is one component of the suggested monoclonal antibody (MAb) combinations for routine immunophenotyping of lymphocytes in peripheral blood using flow cytometry.

Comparison of Technological Characteristics Performance characteristics have been established by clinical evaluation of DAKO Anti-CD3/FITC and Anti-CD4/RPE compared to the individual single reagent predicate devices that quantitatively measure CD3⁺ and CD4⁺ T-cells that have been previously cleared by FDA (DAKO CD3/FITC, Code No. F0818 and DAKO CD4/RPE, Code No. R0805). When flow cytometric tests of peripheral blood samples obtained from apparently healthy adults were

completed, correlation of Anti-CD3/FITC, UCHT1 with DAKO Anti-CD3/FITC and Anti-CD4/RPE approached a direct 1 : 1 comparison for measurement of CD3+ cells. Correlation of Anti-CD4/RPE, MT310 with DAKO Anti-CD3/FITC and Anti-CD4/RPE approached a direct 1 : 1 comparison for measurement of CD4+ cells.

Data for the measurement of CD3+ T-cells by DAKO Anti-CD3/FITC and Anti-CD4/RPE reagent compared to DAKO CD3/FITC gave a correlation greater than 0.96 using the whole blood method for flow cytometry. Data for the measurement of CD4+ T-cells by DAKO Anti-CD3/FITC and Anti-CD4/RPE reagent compared to DAKO CD4/RPE gave a correlation greater than 0.96 using the whole blood method for flow cytometry.

The CD3 antibody clone, UCHT1, was clustered at the First Leukocyte Typing Workshop, Paris, France, 1982. The CD4 antibody clone, MT310, was clustered at the Second Leukocyte Typing Workshop, Boston, 1984.

Linearity testing of DAKO CD3/FITC using JM cells gave the following linear equation:

$$y = 0.02 + 0.98x; r = 0.999$$

Linearity testing of DAKO CD4/RPE using CEM cells gave the following linear equation:

$$y = -0.01 + 1.03x; r = 0.999$$

In addition, reproducibility of DAKO reagents using replicates (from peripheral blood) run on two different flow cytometers was measured at three concentrations of each antigen. Cross-reactivity of Anti-CD3/FITC, plus Anti-CD4/RPE with peripheral blood cells (red blood cells, monocytes, granulocytes, lymphocytes, and platelets) was measured.

Conclusions:

Results of the above testing as well as the information provided by the First and Second Leukocyte Typing Workshops indicate that the DAKO Anti-CD3/FITC plus Anti-CD4/RPE reagent performs as well as DAKO CD3/FITC in the detection and enumeration of CD3⁺ lymphocytes while the DAKO Anti-CD3/FITC plus Anti-CD4/RPE reagent performs as well as DAKO CD4/RPE in the detection and enumeration of CD4⁺ lymphocytes using flow cytometry. Safety of the DAKO Anti-CD3/FITC plus Anti-CD4/RPE reagent and its individual predicate devices is high as all reagents are used for in vitro testing.